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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/835,371 04/1-7/2001 02481.1743 Eugen Uhlmann 5782 22852 7590 04/24/2003 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER EXAMINER LLP SIEW, JEFFREY 1300 I STREET, NW WASHINGTON, DC 20005 ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

F	Application No.	Applicant(s)
Office Action Summary	•	
	09/835,371	UHLMANN ET AL.
	Examiner	Art Unit
The MAILING DATE of this communication app	Jeffrey Siew ears on the cover sheet with the co	1637
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed to the communication of the maining date of this communication of the provision of 37 CFR 1.136(a). In no event, however, may a reply be timely filed to the communication of the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed to the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed to the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed to the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed to the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed to the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed to the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of 50 CFR 1.136(a). In no event, however, may a reply be timely filed the provision of		
1) Responsive to communication(s) filed on 19 February 2003.		
2a) This action is FINAL. 2b) ☐ Thi	n) ☐ This action is FINAL . 2b) ☒ This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4) Claim(s) 1-81 is/are pending in the application.		
4a) Of the above claim(s) <u>26-29,33-39 and 81</u> is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) <u>1-25,31,32,40-80</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement. Application Papers		
9)☐ The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>17 April 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a)⊠ All b)□ Some * c)□ None of:		
Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)		(PTO-413) Paper No(s) atent Application (PTO-152)

Application/Control Number: 09/835,371 Page 2

Art Unit: 1637

DETAILED ACTION

Location of Application

 The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1637, and is assigned to Patent Examiner Jeffrey Siew.

Information Disclosure Statement

 The I.D.S. filed 10/26/01 paper no. 3 and filed 3/15/02 paper no. 6 do not appear in the file wrapper. It is respectfully requested that a courtesy copy of I.D.S. and references be submitted.

Election/Restrictions

3. Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that groups are sufficiently related that a search of any one group of claims would encompass a search of the other claims and no undue burden exist. This is not found persuasive because group I and group II are related as process of making and product made. A plurality of different methods may be used to synthesize the product without using solid support requirements of Group III such as in solution. Moreover the product may be employed in plurality of different methods including sequencing and anti-sense inhibition.

The requirement is still deemed proper and is therefore made FINAL.

Application/Control Number: 09/835,371

Art Unit: 1637

4. Claims 26-29 & 33-39 & 81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-20, 45-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulhmann et al (Nucleosides & Nucleotides vol. 16(5&6) pp. 603-608 1997).

Ulhmann et al teach polyamide nucleic acids that bind to complementary DNA and RNA with N-(2aminoethyl)glycine units (see whole document esp. page 603, 604 & 607 structures). They teach PNAs as antisense therapeutics and DNA diagnostics (see page 604). They teach synthesis from derivatives off solid support (see page 604).

The claims in the broadest reasonable interpretation wherein q is zero and m is zero and n is zero and q-poly} is Formula IIIB.

 Claims 1-20,23,25,30-32 &40-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Breipohl et al (US6,046,306 April 4,2000). Breipohl et al teach polyamide nucleic acids. They teach various labels that may be associated with PNA such biotin, fluorescein (see col. 5 lines 1-10).

The claims in the broadest reasonable interpretation wherein q is zero and m is zero and n is zero and {poly} is Formula IIIB.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
 obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulhmann et al (Nucleosides & Nucleotides vol. 16(5&6) pp. 603-608 1997) in view of Weiler et al (NAR vol. 15 no. 14 pp. 2792-2799 1997).

Art Unit: 1637

The teachings of <u>Ulhmann et al</u> are described previously.

Ulhmann et al do not teach microarray supports.

Weiler et al teach the construction of PNA oligomer arrays for hybridization assays (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Weiler et al's teaching of microarrays to Ulhmann et al's PNA in order to construct oligonucleotide sensors. As Weiler et al states the PNA may be used in arrays because the PNA provide high thermal stability and are instrumental for screening sequences (see page 2792-3). It would have been prima facie obvious to apply Weiler et al's teachings of microarrays to Ulhmann et al's PNAs in order to increase hybridization specificity and affinity in microarray screening.

Claims 23 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breipohl et al (US6,046,306 April 4,2000) in view of Weiler et al (NAR vol. 15 no. 14 pp. 2792-2799 1997).

The teachings of Breipohl et al are described previously.

Breipohl et al do not teach microarray.

Weiler et al teach the construction of PNA oligomer arrays for hybridization assays (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Weiler et al's teaching of microarrays to Ulhmann et al's PNA in order to construct oligonucleotide sensors.

As Weiler et al states that the PNA may be used in arrays because the PNA provide high thermal stability and are instrumental for screening sequences (see page 2792-3). It would have been

Art Unit: 1637

<u>prima facie</u> obvious to apply Weiler et al's teachings of microarrays to Ulhmann et al's PNAs in order to increase hybridization specificity and affinity in microarray screening.

 Claims 21 & 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulhmann et al (Nucleosides & Nucleotides vol. 16(5&6) pp. 603-608 1997) in view of Manoharan et al (US6,043,352 March 28, 2000).

The teachings of <u>Ulhmann et al</u> are described previously.

<u>Ulhmann et al</u> do not teach binding to HA ras translation start or pharmaceutical composition.

Manoharan et al teach oligonucleotides used in pharmaceutical compositions with pharmaceutically acceptable diluent or carrier for diagnostics or therapeutics (see whole doc. esp. abstract and col. 8 line 45-50). Moreover they teach targeting Ha ras initiation translation region (see col. 16 lines 31-35). They also teach the use of PNAs (see col.3 lines 1-5). They teach modification with labels such as fluorescein and biotin(see col. 3 lines 5-7).

One of ordinary skill in the art would have been motivated to apply Manoharan et al's teaching of binding to antisense inhibition with Ulhmann et al's PNAs in order inhibiting gene expression. As Manoharan et al teach that the oligonucleotides bind to target DNA or RNA for therapeutic antisense inhibition, which interfere with protein production ,increase maximum therapeutic effect and minimal side effects (see col. 1lines 14-26). It would have been prima facie obvious to apply Manoharan et al's teaching of antisense inhibition to Ulhmann et al's

Art Unit: 1637

PNA's which provide increase hybridization efficiency in order to increase the inhibition efficiency of oligonucleotides to target DNA

SUMMARY

10. No claims allowed. The broad genus is taught by the prior art. However, the elected species (see response filed 2/19/03) is free of the prior art.

CONCLUSION

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey. Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the <u>Tracey Johnson</u> for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Application/Control Number: 09/835,371

Art Unit: 1637

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

JEFFREY SIEW PRIMARY EXAMINE

Page 8

April 14, 2003